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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,290	11/28/2000	Walter Muller		5693

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,290	Applicant(s) MULLER ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-41* is/are pending in the application.

4a) Of the above claim(s) *34-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' preliminary amendment, declaration, request for extension of time and IDS, all filed 11/28/2000; revocation of power of attorney and new power of attorney, filed 4/16/2001; and election filed 1/28/2002.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 18-33, in Paper No. 9, is acknowledged. The traversal is on the ground(s) that unity of invention exists because the claimed process inherently produces the claimed product with technical relationship being present between the claimed process and the claimed product. This is not found persuasive because group I reads on a matrix based on acrylate polymer or silicone polymer. If acrylate-based polymer is used, no PVP is required, but if silicone-based polymer is used PVP is required. Thus, the process of group II is only applicable on silicon-based polymer and not on acrylate-based polymer. Thus, the two groups do not have the same technical features. Furthermore, the product of group I requires the product to be substantially free from inorganic silicate, while the process of group II requires the inorganic silicate. In any event, under PCT article 13, applicants are entitled to a single invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 34-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18-43 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant's disclosure does not provide sufficient information regarding the degree or the amount of the inorganic silicate that is considered "substantially free".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 18-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "effective" is not indicative what it is effective for.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 18-20, 22, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang et al.

Chiang et al. disclosed a N-0923, (-)-5,6,7,8-tetrahydro-6-[propyl-1[2-(2-thienyl) ethyl]amino]-1-naphthalenol in a transdermal delivery system. The system comprises the drug in a pressure sensitive adhesive matrix based on silicone or acrylate, propylene glycol, and permeation enhancer (page 710, left col., last paragraph; page 711, right col., table 1). The system comprises a release film and a casting film, i.e. backing (page 710, right col., first paragraph). The solubility of particular drug in

particular adhesive is inherent. The reference silence regarding the inorganic silicates, indicating the system is free or substantially free of them.

10. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/07468 ('468).

WO '468 disclosed a transdermal drug delivery device comprising a matrix containing the drug in a polymer base; backing layer; and release liner (abstract; page 3, lines 13-29). The drugs included (-)-5,6,7,8-tetrahydro-6-[propyl-1[2-(2-thienyl) ethyl]amino]-1-naphthalenol in an amount of 1-20 % (page 7, lines 27-29; page 8, lines 1-2). The polymers are silicone-based or acrylate-based with solubility of drugs less than 1 % (page 5, lines 1-3, 33-35; page 11, lines 25-30). The matrix further comprises a permeation enhancer include fatty acids (oleic acid), fatty ester, and fatty alcohol (oleyl alcohol), (page 6, lines 6-12). The matrix comprises a hydrophilic polymer such as propylene glycol and polyethylene glycol (page 6, lines 21-23). The reference discloses the inorganic silicate as low as 2 % (page 17, lines 19-20).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 18-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiang et al. or WO '468 each standing by itself or in combination.

The teachings of the references are discussed under 102 rejections above. However, the references do not teach the species of the acrylate-based adhesive; and Chiang's reference does not teach the particular permeation enhancers disclosed by the applicants, nor the amount of the drug in the adhesive matrix.

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. Therefore, the ratios and weight percents of the drug and the inorganic silicate instantly claimed are not considered critical absent evidence showing unexpected and superior results.

It is also within the skill in the art to select the species of the acrylate-based polymer as well as the permeation enhancers.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver (-)-5,6,7,8-tetrahydro-6-[propyl-1[2-(2-thienyl) ethyl]amino]-1-naphthalenol in polymer matrix of silicone or acrylate, and adjust the amount of the inorganic silicate in order to achieve the desired cohesiveness of the matrix layer with reasonable expectation of success of the delivered device in providing effective amount of dopamine agonists to patients suffering from Parkinsonism.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Izaak et al. and Swart et al., both disclosed transdermal administration of dopamine agonists. US 5,043,482 disclosed topical administration of (-)-5,6,7,8-tetrahydro-6-[propyl-1[2-(2-thienyl) ethyl]amino]-1-naphthalenol. US 5,382,569 disclosed (-)-5,6,7,8-tetrahydro-6-[propyl-1[2-(2-thienyl) ethyl]amino]-1-naphthalenol for treating Parkinsonism.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone

number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600